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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,005	09/11/2003	Sven Bulow	KLAUS3.001AUS	7758

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/661,005	BULOW ET AL.
	Examiner	Art Unit
	Kimberly Chong	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/27/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *18-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-17, in the reply filed on 06/27/2005 is acknowledged.

Status of the Application

Claims 1-19 are pending in the application. Claims 18-19 are withdrawn. Claims 1-17 are currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the phrase "agent of interest". It is unclear what is meant by exposing the cells to an "agent of interest" The phrase " agent of interest " is not defined by the claim and the specification does not provide any information on what a particular agent could be and therefore the claim is indefinite for failing to particularly pointing out what applicant regards as the invention.

Claim 14 recites the phrase "enzymatic activities on the specific location are assayed". It is unclear what assaying enzymatic activities means. Does this phrase mean assaying enzymatic activities in the cells or assaying enzymatic activities of the siRNA molecule?

Claim 13 recites the limitation "wherein specific proteins" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "wherein enzymatic activities" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "wherein one or more specific mRNAs" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-6, 8-11 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Harborth et al. (Journal of Cell, 2001).

Claim 1 is drawn to a method for investigating the biological effect of a siRNA directed against one gene present in a cell comprising plating cells on a support, adding the siRNA and detecting the biological effect of the siRNA on the cells. Claims 2-6 recite the siRNA is obtained by enzymatic digestion, by dicer or RNase III-type enzymes, of double stranded nucleotides or by chemical synthesis at the predetermined locations on the surface of the support, the double stranded nucleotides are RNA corresponding to a partial or completed coding sequence of the corresponding genes. Claims 8-11 are further limiting by reciting the support is selected from a group as listed and the locations for the siRNA are isolated by a physical barrier. Claims 12-13 limit claim 1 by reciting the detection of the biological effect is determined by cell division, proliferation, differentiation or apoptosis and further the proteins of the cells are analyzed by western analysis.

Harborth et al. teach a method of investigating the effect of a siRNA targeted against a human RNA in Hela cells comprising plating cells on a 24-well cell culture plate and transfecting a chemically synthesized siRNA molecule (see page 4558, last paragraph). Harborth et al. further teach detection of the biological effect is determined by cell differentiation and analysis of protein extracts by western blotting (see Figure 6).

Thus, Harborth et al. anticipates claims 1-5, 8-10 and 12-13 of the instant application.

Claims 1, 4, 8 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Caplen et al. (Gene, 2000).

Claim 1 is drawn to a method for investigating the biological effect of a siRNA directed against one gene present in a cell comprising plating cells on a support, adding the siRNA and detecting the biological effect of the siRNA on the cells. Claims 4, 8 and 15 recite the support is selected from the group as listed and the mRNAs are analyzed by northern analysis.

Caplen et al. teach a method of investigating the effect of a siRNA targeted against an RNA in a cell comprising transfecting cells with a dsRNA and measuring expression of green fluorescent protein by northern blot analysis.

Thus, Caplen anticipates claims 1, 4, 8 and 15 of the instant application.

Claims 1-6, 8, 10-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by McManus et al. (RNA, 2002).

Claim 1 is drawn to a method for investigating the biological effect of a siRNA directed against one gene present in a cell comprising plating cells on a support, adding the siRNA and detecting the biological effect of the siRNA on the cells. Claims 2-6, 8 and 15 recite the siRNA is obtained by enzymatic digestion, by dicer or RNase III-type enzymes, of double stranded nucleotides or by chemical synthesis at the predetermined locations on the surface of the support, the double stranded nucleotides are RNA corresponding to a partial or completed coding sequence of the corresponding genes, the double stranded RNA nucleotides are short hairpin RNA (shRNA) or microRNA and the support is selected from the group as listed and the mRNAs are analyzed by northern analysis.

McManus et al. teach a method of investigating the effect of a short hairpin RNA or microRNA targeted against an RNA in a cell comprising transfecting cells with a shRNA and measuring expression of mRNA by northern blot analysis (see page 848, materials and methods). The specification of the instant application defines microRNA as being able to form hairpin structures and therefore would be encompassed in the shRNA as described by McManus.

Thus, McManus anticipates claims 1-6, 8, 10-11 and 15 of the instant application.

Claims 1-6, 8, 10-14, 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Fosnaugh et al. (US 2003/0148507).

The instant claims are drawn to a method for investigating the biological effect of a siRNA directed against one gene present in a cell comprising plating cells on a support, adding the siRNA and detecting the biological effect of the siRNA on the cells. Claims 2-6 recite the siRNA is obtained by enzymatic digestion of double stranded nucleotides or by chemical synthesis at the predetermined locations on the surface of the support, the double stranded nucleotides are RNA corresponding to a partial or completed coding sequence of the corresponding genes and further recite the double stranded RNA nucleotides are short hairpin RNA or microRNA. Claims 8 and 10-11 are further limiting by reciting the support is selected from a group as listed and the locations for the siRNA are isolated by a physical barrier. Claims 12-13 and 15 limit claim 1 by reciting the detection of the biological effect is determined by cell division, proliferation, differentiation or apoptosis and further the proteins of the cells are analyzed by western

analysis and the mRNAs are analyzed by northern analysis. Claims 16-17 recite determination of the biological effect is by RT-PCR or real-time detection.

Fosnaugh et al. teach a method of investigating the effect of a siRNA targeted against a human RNA in lung epithelial cells comprising plating cells on a culture plate and transfecting a siRNA molecule (see Example 7, paragraph 0263). Fosnaugh et al. further teach analysis of protein extracts by western blotting (see paragraph 0270) and analysis of total RNA by RT-PCR and real time PCR assays (see paragraph 0268).

Thus, the instant claims 1-6, 8, 10-14 and 16-17 are anticipated by Fosnaugh et al.

Claims 1-4, 7-11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Tzertzinis et al. (US 2004/0038278).

Claim 1 is drawn to a method for investigating the biological effect of a siRNA directed against one gene present in a cell comprising plating cells on a support, adding the siRNA and detecting the biological effect of the siRNA on the cells. Claims 2-4 recite the siRNA is obtained by enzymatic digestion of double stranded nucleotides or by chemical synthesis at the predetermined locations on the surface of the support, the double stranded nucleotides are RNA corresponding to a partial or completed coding sequence of the corresponding genes. Claims 7-11 are further limiting by reciting the enzymatic digestion is performed on the double stranded RNA nucleotides by DICER or RNase III-type enzymes, the support is selected from a group as listed and the locations for the siRNA are isolated by a physical barrier. Claim 13 limits claim 1 by reciting the proteins of the cells are analyzed by western analysis.

Tzertzinis et al. teach a method of investigating the effect of a siRNA targeted against a human RNA in mammalian cells comprising plating cells on a culture plate and transfecting a dsRNA molecule that is enzymatically digested into a siRNA (see paragraph 0184). Tzertzinis et al. further teach analysis of protein extracts by western blot (see paragraph 0187).

Thus, the instant claims 1-4, 7-11 and 13 are anticipated by Tzertzinis et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Kimberly Chong
Examiner
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1635